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DECLARATION OF CONFORMITY

Business Unit Name/Address: Caire, Inc.
Chart BioMedical Division
1800 Sandy Plains Industrial Pkwy, Suite 316
Marietta, GA 30066 USA

Manufacturing Facilities Address: Caire, Inc. Chart BioMedical Ltd.
2000 Airport Industrial Drive Unit 2 – Maxdata Centre, Downmill Rd
Ball Ground, GA 30107 Bracknell, Berkshire, RG12 1QC
USA United Kingdom

TPED/MDD Representative: MPS
Medical Product Service GmbH
Borngasse 20
35619 Braunfels, Germany

Product Families: Portable Liquid Oxygen Units
Base Liquid Oxygen Units

MDD Equipment Class: Class IIa, MDD appendix II

Global Medical Device Nomenclature 35910-Portable Liquid Oxygen Units
(GMDN) Code: 35221-Base Liquid Oxygen Units

This declaration applies to all CE marked devices manufactured from the date of issuance until it is either superseded by another declaration or withdrawn. I, the undersigned, hereby declare the equipment specified above, is in accordance with the following Directives:

1.) Module D1 of the **European Council Directive 99/36 EC for Transportable Pressure Equipment Directive**
(Certificate Number: 05/US/919))

2.) Appendix II of the **Medical Devices Directive 93/42/EC**
(Certificate Number: 05/US/920)

and the following Standard:

1.) **EN – ISO 13485 (2003)**
(Certificate Number: 05/US/920)

Notified Body: APRAGAZ (0029)
Vilvoordesesteeweg, 156
Chaussée de Vilvorde, 156
1120 Brussels, Belgium

Start of Pi Marking: 13 December 2002
Start of CE Marking: 12 February 1998

Model(s): N/A Serial Number(s): N/A Invoice Number / Order Number N/A

To the best of my knowledge, the information above is accurate and was in effect from Mar 07, 2008, thru to Jan 08, 2009. This applies to all listed products above manufactured within the effective dates.



Signature: _____
Position: Quality or CSR or Operations or Regulatory

Date: Mar 20, 2024

Name (Print): Ted Vlahopoulos